

AMENDMENTS

In the Claims

Please cancel claims 2, 3, 15, 16, 31-35, 43-50 and 56, amend claims 1, 5, 6, 14, 17, 18 and 52 as follows:

1. (Currently Amended) A biological fluid sampling and analyte concentration measurement device, said device comprising:
 - (a) at least one skin-piercing member comprising a biological fluid access opening;
 - (b) an electrochemical cell for measuring the concentration of analyte within the biological fluid, wherein the cell comprises at least one porous electrode; and
 - (c) a ~~fluid transfer medium~~ hydrophilic porous material in fluid communication with the at least one piercing member and with the at least one porous electrode, wherein ~~fluid transfer medium~~ hydrophilic porous material transfers biological fluid present at the access opening of the at least one piercing member to the electrochemical cell, wherein the porous material comprises a distal portion associated with the at least one piercing member and a proximal portion adjacent to the at least one porous electrode, wherein the proximal portion is more porous than the distal portion.
2. (Cancelled)
3. (Cancelled)
4. (Currently Amended) The device of claim ~~3~~ 1 wherein the proximal portion is about 10 to 100 times more porous than the distal portion.
5. (Currently Amended) The device of claim 1 wherein the ~~fluid transfer medium~~ hydrophilic porous material transfers biological fluid by means of a capillary force exerted on the biological fluid in its presence.
6. (Currently Amended) The device of claim ~~2~~ 1 wherein the porous material is selected from the group consisting of polymers, ceramics, glass and silica.

7. (Original) The device of claim 1 wherein the electrochemical cell comprises two spaced-apart electrodes defining a reaction chamber and a selected reagent for chemically reacting with an analyte targeted for measurement.
8. (Original) The device of claim 7 wherein the distance between the electrodes is from about 10 to 300 microns.
9. (Original) The device of claim 8 wherein the distance between the electrodes is from about 10 to 150 microns.
10. (Original) The device according to claim 7 wherein the reagent is located on a surface of at least one electrode facing the reaction chamber.
11. (Original) The device of claim 7 wherein both electrodes are porous.
12. (Original) The device of claim 11 further comprising a housing having at least one vent hole for venting air from within the electrochemical cell.
13. (Original) The device of claim 1 wherein the biological fluid is interstitial fluid and the analyte is glucose.
14. (Currently Amended) The device of claim ~~2~~ 1 further comprising a hydrophilic gel.
15. (Cancelled)
16. (Cancelled)
17. (Currently Amended) The device of claim ~~15~~ 1 wherein the hydrophilic porous material comprises pores ~~have~~ having diameters in the range from about 0.1 to 50 μm .

18. (Currently Amended) The device of claim 17 wherein the pore diameters are in the range from about 0.1 to 10 μm .

19. (Original) A biological fluid sampling and analyte concentration measurement device, said device comprising:

- (a) an array of micro-needles, each micro-needle having an access opening;
- (b) a layer of porous material over the array;
- (c) a first layer of conductive material over the layer of porous material, wherein the first layer of conductive material is porous and further wherein the access openings, the layer of porous material and the first layer of conductive material provide a fluid transfer pathway; and
- (d) a second layer of conductive material, wherein the first layer of conductive material and the second layer of conductive material are spaced-apart, wherein biological fluid present at the access openings is caused to be transferred to the space between the first and second layers of conductive material.

20. (Original) The device of claim 19 further comprising a layer of insulating material over the second layer of conductive material.

21. (Original) The device of claim 19 wherein the array of micro-needles comprises an insulating material.

22. (Original) The device of claim 19 further comprising a layer of reagent material between the first and second layers of conductive material wherein an analyte targeted for measurement present in the in the space between the first and second layers of conductive material chemically reacts with the reagent.

23. (Original) The device of claim 22 wherein the layer of reagent material contacts either the first layer of conductive material, the second layer of conductive material or both.

24. (Original) The device of claim 19 wherein the second layer of conductive material is porous.

25. (Original) The device of claim 24 further comprising an insulating layer over the second layer of porous conductive material, wherein the insulating layer has a venting hole there through.

26. (Original) The device of claim 19 wherein the biological fluid being sampled is interstitial fluid.

27. (Original) The device of claim 26 wherein the analyte is glucose and the reagent comprises a glucose oxidizing enzyme and a mediator.

28. (Original) The device of claim 27 wherein the enzyme is selected from a group consisting of glucose oxidase and glucose dehydrogenase.

29. (Original) The device of claim 28 wherein the mediator is ferricyanide.

30. (Original) The device of claim 19 wherein the micro-needles of the array of micro-needles have varying lengths.

31.-35. (Cancelled)

36. (Original) A system for sampling biological fluid from the skin of a patient and measuring a target analyte within the biological fluid, the system comprising:

(a) at least one device according to claim 1; and

(b) a control means in electrical communication with the at least one device, the control means comprising:

(1) means for sending an electrical input signal to the device and for receiving an electrical output signal from the device, and

(2) a software algorithm which automatically calculates and determines the concentration of the target analyte in the biological sample upon receipt of the electrical output signal.

37. (Original) The system of claim 36 further comprising a display means in electrical communication with the control means for displaying information in the form of electrical signals received from the control means related to the sampling of the biological fluid and the measuring of the target analyte.

38. (Original) The system of claim 36 further comprising a housing wherein the control means is located within the housing and the device is mounted to the housing.

39. (Original) The system of claim 37 wherein the device is mounted to the housing by means of a lock-and-release mechanism.

40. (Original) The system of claim 38 further comprising user input buttons on the housing for providing user input to the control unit.

41. (Original) The system of claim 38 further comprising a display means on the housing for displaying information from the control means.

42. (Original) The system of claim 38 wherein the housing has a hand-held configuration.

43.-50. (Cancelled)

51. (Original) A method for sampling a biological fluid within the skin of a patient and for measuring the concentration of one or more target analytes contained therein, the method comprising the steps of:

providing a biological fluid sampling and analyte measuring system according to claim 36 comprising a first sensor device operatively coupled to a control means;

operatively applying the sensor device to the patient's skin wherein the system samples the patient's biological fluid and measures the concentration of the one or more target analytes therein;

removing the sensor device from the patient's skin;

removing the first sensor device from the control means;

operatively coupling a second sensor device to the control means; and

repeating the above steps until the desired number of samplings and measurements have been performed.

52. (Currently Amended) A kit for sampling a biological fluid from the skin of a patient and for measuring the concentration of a analyte within the sampled biological fluid, the kit comprising:

~~at least one device according claim 1; and~~

~~a control means~~ a system according to claim 36.

53. (Currently Amended) The kit of claim 52 wherein the ~~at least one~~ biological fluid sampling and analyte concentration measurement device is disposable and the control unit is reusable.

54. (Original) A kit for sampling a biological fluid from the skin of a patient and for measuring the concentration of a analyte within the sampled biological fluid, the kit comprising:

a plurality of disposable devices according to claim 1.

55. (Original) The kit of claim 54 further comprising a support member wherein the plurality of micro-needles are arranged in an array on the support member.

56. (Cancelled)